REMARKS

The Office action dated March 16, 2010 is acknowledged. Claims 1-10 and 12-18 are pending in the instant application. Claims 2-4, 6-10 and 14-18 have been withdrawn and claims 1, 5, 12 and 13 are rejected. By the present Office Action response, claims 1, 5 and 13 have been amended, and claims 19-28 are newly added.

Claim 1 has been amended to further define the dopamine agonist as being selected from the group consisting of lisuride, bromocriptine, pramipexole, ropinirole, rotigotine, terguride, cabergoline, piribedile, pergolide and 4-propyl-9-hydroxynaphthoxazine (PHNO), with apomorphine being excluded. Support for this amendment may be found throughout the specification, such as at paragraph [00020] and claim 3. Although claim 3 is specified as withdrawn, the Applicants respectfully question whether this designation is accurate since the subject matter of claim 3 was not identified as a separate species in the Office action dated September 9, 2009.

Claim 1 has also been amended to further define a combination of L-dopa and an anticholinergically active substance as being selected from the group consisting of bornaprine, metixene and orphenadrine. Support for this amendment may be found throughout the specification, such as at paragraph [00022] and claim 5.

Claim 5 has been amended to refer to said combination of a dopamine agonist and an anticholinergically active substance of claim 1 and further define this limitation insofar as the anticholinergically active substance is concerned as being selected from the group consisting of bornaprine, metixene and orphenadrine, as in the third paragraph of claim1.

Claim 13 has been amended to specify that "at least two active substances of the active substance combination are contained in different layers or compartments of the transdermal therapeutic system. Support for this amendment may be found throughout the specification, such as at paragraph [00046].

Support for new claims 19-28 may be found as follows:

- Claim 19 relates to the embodiment described in paragraph [00052] of the specification.
- Claim 20 depends from claim 5 and further states that biperidene, trihexyphenidyl, procyclidine, scopolamine, atropine, benzatropine and nicotine may be present.
- Claim 21 corresponds to present claim 3.
- Claims 22 and 23 further define the dopamine agonist of claim 1.
- Claim 24 combines limitations of claims 1 and 13.
- Claim 25 combines limitations of claims 1 and 19.
- Claims 26-28 are supported by paragraph [000047] of the specification.

Reconsideration is respectfully requested in light of the arguments and amendments made herein. No new matter has been added.

Priority

The Examiner points out in the Office action that an English translation of the priority document has not been received. The English translation was submitted with the U.S. National phase filing, but upon discussion with the Examiner it is believed that the English translation may have been incorrectly processed by the USPTO and never entered into the records of the present application. Thus, a substitute copy of the English

translation of the priority document is submitted herewith.

Rejection of claim 13 under 35 U.S.C. 112, second paragraph

The Examiner has rejected claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Examiner argues that in claim 13 the Applicants have not specifically set out if the at least two active agents are contained in different layers or compartments individually or together. Thus, the Examiner requests clarification on this feature.

Claim 13 has been amended to specify that "at least two active substances of the active substance combination are contained in different layers or compartments of the transdermal therapeutic system." It is submitted that the amendment to claim 13 renders the claim sufficiently clear that one of the at least two active substances is contained in one layer of the different layers, and another one of the at least two active substances is contained in another/different layer. Withdrawal of this rejection is requested.

Rejection of claims 1, 5 and 12 under 35 U.S.C. 102(b)

Claims 1, 5 and 12 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,193,992 (El-Rashidy, et al.). The Examiner states that the El-Rashidy, et al. reference discloses the administration of apomorphine and that the apomorphine can be administered in conjunction with a parasympathetic depressant, such as scopolamine. The Examiner states that while the exemplified embodiments of El-Rashidy, et al. are drawn to sublingual administration, the Examiner's position is that the reference discloses that the compositions can be formulated as transdermal devices.

The Examiner further states in the Office action that while the combination of apomorphine and scopolamine are not exemplified, the combination is presented in a finite grouping of agents and so one skilled in the art would immediately envision their use together.

The Examiner still further states that the recitation of "for treatment of Parkinson's Disease" is regarded as future intended use and thus not given patentable weight. Thus, the Examiner argues that the disclosure of El-Rashidy, et al. meets the limitations of the present claims.

Claims 1, 5 and12 have also been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,963,568 (Schoenleber, et al.). The Examiner states that the Schoenleber, et al. reference discloses compounds which are selective dopamine agonist useful for treating disorders characterized by abnormal dopamine levels, including Parkinson's disease. The Examiner argues that the reference additionally discloses that L-Dopa, when used in conjunction with a peripheral aromatic amino acid decarboxylase inhibitor, and often supplemented with anticholinergic agents, has been shown to be useful in the treatment of Parkinson's disease. The Examiner further argues in the Office action that the compounds disclosed by Schoenleber, et al. are administered in conjunction with the L-Dopa and anticholinergic agents while the anticholinergic agents disclosed include benztropine, biperiden, ethopropanizine, procyclidine, trihexylpenidyl and the like. Thus, the Examiner concludes that the composition can be administered as a transdermal patch and so the reference meets the limitations of the present claims.

The Applicants respectfully disagree with the Examiner's conclusions and submit that the present invention as defined in the present claims is patentably distinct from the invention disclosed in the cited prior art references. In particular, as discussed above, claim 1 has been amended to refer to a combination of a dopamine agonist and an anticholinergically active substance, wherein the dopamine agonist is selected from a group which does not include apomorphine (which is taught by El-Rashidy, et al.). It is submitted that El-Rashidy, et al. do not teach or disclose any dopamine agonists other than apomorphine since the described therapeutic effect of El-Rashidy, et al. (i.e., sexual dysfunction treatment) was specific for this particular substance.

It is also submitted that the ganglionic agents or antiemetic agents taught by El-Rashidy, et al. (col. 5, lines 50 – col. 6, line 5) are only required when apomorphine is used as an active substance, as this substance tends to induce nausea/vomiting which must therefore be suppressed by co-administering a suitable antiemetic agent.

In view of the above, it is submitted that El-Rashidy, et al. fail to teach each and every limitation of the present claims, and therefore fail to anticipate the present invention as set forth in the present claims. Withdrawal of this rejection is respectfully requested.

The Applicants also submit that Schoenleber, et al. fail to teach each and every limitation of the presently claimed invention. Schoenleber, et al. fail to disclose a combination of L-dopa and an anticholinergically active substance selected from the group of bornaprine, metixene and orphenadrine. Moreover, Schoenleber, et al. fail to teach the specific dopamine agonists recited in the second paragraph of present claim 1.

Thus, it is submitted that Schoenleber, et al. clearly fail to teach each and every limitation of the present claims, and therefore fail to anticipate the present invention as set forth in the present claims. Withdrawal of this rejection is also respectfully requested.

Rejection of claims 1, 5 and 12-13 under 35 U.S.C. 103(a)

Claims 1, 5 and 12 have been rejected as being unpatentable over U.S. Patent No. 5,614,178 (Bloom, et al.). The Examiner states that Bloom, et al. disclose transdermal devices comprising an active agent which is selected from numerous classes of drugs, including anticholinergic drugs including scopolamine and L-dopa. The Examiner further states that it is generally considered to be prima facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. In this regard, the Examiner states that the motivation for combining them flows from their having been used individually in the prior art and from them being recognized in the prior art as useful for the same purpose. Thus, the Examiner concludes it would have been obvious to have combined the two known agents of Bloom, et al., which are used for the same purpose, into a transdermal device.

Claim 13 is rejected as being unpatentable over El-Rashidy, et al. in view of U.S. Patent No. 4,877,618 (Reed, Jr.) or alternatively Schoenleber, et al. in view of Reed, Jr. The Examiner points out that neither El-Rashidy, et al. nor Schoenleber, et al. disclose the configuration of the transdermal device. The Examiner refers to Reed, Jr. for disclosing transdermal devices for drug delivery, the device comprising a plurality of adhesive laminae containing the drug to be transdermally delivered. The Examiner's conclusion is

that one skilled in the art would have a reasonable expectation of making a transdermal delivery device comprising the teachings of both El-Rashidy, et al. and Schoenleber, et al. with those of Reed, Jr. and that it would have been obvious to have used the transdermal device of Reed, Jr. with the formulation of El-Rashidy, et al. and Schoenleber, et al. to have arrived at the presently claimed invention.

It is respectfully submitted that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. The Applicants respectfully submit that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider the teachings of the cited prior art alone or in combination, each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

Regarding the Bloom, et al. reference, the Applicants respectfully disagree with the Examiner's conclusion. The Examiner has referenced column 5, lines 50-55 of Bloom, et al. It is respectfully submitted that while this passage teaches substances such as scopolamine, atropine, L-dopa, procyclidine, trihexypheridyl, etc., it does not appear to teach or suggest any of the specific substances recited in the second and third paragraphs of claim 1 as presently amended. Thus, the reference fails to teach or suggest each and

every limitation of the presently claimed invention.

The Applicants also respectfully disagree with the Examiner's rejection of claim 13 as being obvious, for at least the numerous deficiencies of El-Rashidy, et al. and Schoenleber, et al. set forth above. Moreover, Reed, Jr. fails to make up for the deficiencies of El-Rashidy, et al. and Schoenleber, et al. Reed, Jr. in fact discloses a transdermal drug delivery device which comprises a plurality of different layers. However, Reed, Jr. does not teach or suggest that these different layers might contain different active substances. To the contrary, Reed, Jr. consistently refers to "the drug" throughout the reference which clearly implies that a single drug is incorporated into the layers of the device taught therein. It would also be evident to one skilled in the art that a single drug is necessary in Reed, Jr. to achieve the desired effect of delivering the drug at a slowly, preferably uniformly, declining rate (col. 2, lines 28-65). Reed, Jr. would teach away from the present invention and so would not be relied upon by one skilled in the art.

In view of the above, the Applicants respectfully request that the obviousness rejections be withdrawn.

Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicants strongly urge that the obviousness-type rejection and anticipation rejections be withdrawn. The Examiner is invited to call the undersigned if

there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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